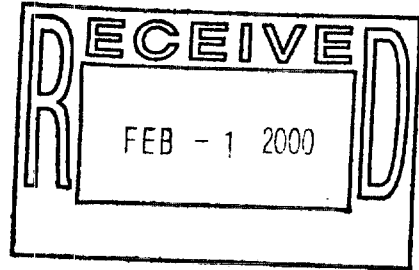




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January 25, 1999



The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statement:

- (1) St. John's Wort-IMT contains 300 mg of 0.3% hypericin per capsule plus inositol and kelp to promote mental health and maintain emotional balance.
- (2) The inositol and kelp contained in Standard Process' St. John's Wort-IMT complement the herb's natural strength and ability to induce a calming effect and promote harmony among the different parts of the nervous system.
- (3) Today, health care practitioners in many parts of the world use St. John's wort to stabilize mood. Inositol, in similar fashion, works to bring about greater emotional tranquility. Kelp, a rich source of B complex vitamins, helps support healthy brain tissue and supports the membranes surrounding the brain, spinal cord, and sensory nerves.
- (4) Reduces feelings of irritability.
- (5) Standard Process' St. John's Wort-IMT contains inositol to boost its ability to increase nervous system response to stimuli. When the nervous system operates at a higher rate of efficiency, anxious feelings and exaggerated responses to life's everyday ups and downs are kept to a minimum, helping to create a more peaceful mental state.
- (6) Enhances immune response.
- (7) St. John's wort can help support the body's natural resistance mechanisms.

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**Standard  
Process®**

- (8) Combines St. John's wort with the nutritional compounds found in the Standard Process product Min Tran to support the healthy, balanced function of the central nervous system. Calcium and magnesium found in Min-Tran help relax the nervous system and promote healthy transmission of nerve impulses.

This statement is made for a dietary supplement containing a proprietary blend of calcium lactate, inositol, St. John's wort (leaves and flowers) powder, magnesium citrate, alfalfa meal, and carrot (root) powder. Other ingredients include kelp powder, calcium stearate, and carrot oil. The name of the product is St. John's Wort-IMT.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

